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510(k) SUMMARY K003832 1 OF 2

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Anatomical Shoulder Cemented Humeral Stem.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH 6341 Baar, Switzerland
US Designated Agent:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	December 8, 2000
Contact Person:	Mitchell A. Dhority, RAC Manager, Regulatory & Clinical Affairs
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis – 21 CFR 888.3660
Common/Usual Name:	Humeral Stem Component
Trade/Proprietary Name:	Sulzer Orthopedics Anatomical Shoulder Cemented Humeral Stem

PRODUCT DESCRIPTION

The purpose of this Special 510(k) submission is to obtain clearance for a change in material from stainless steel alloy (ISO 5832-9) to cobalt chrome alloy (ISO 5832-4).

The CoCr humeral stem has the same design as the previously cleared stainless steel version. In general, the proximal aspect of the stem is "trumpet shaped" to match the metaphysis of the humeral shaft. Rotational stability is ensured by a proximal fin on the lateral aspect. Holes in the fin and stem body allow for attachment of the tuberosities via sutures/wires. The component is available in four sizes which are determined by the diameter of the stem. Longer stem lengths in these same base sizes are available for revision applications.

The stem design features a slit-ball head fixed at an angle of 135°. An impact screw and expansion cone are inserted through a shaft in the lateral aspect of the stem and into the slit-ball head at the time of surgery. This forces the slit-ball feature to spread open allowing fixation of one of the humeral heads used with the system. The use of the slit ball has the advantage of allowing fixation of the head in a variety of angles. A traumatology cone identical to the expansion cone, except with positioning pegs for head placement, is also available.

The stem may be used with previously cleared Anatomical Shoulder Humeral Heads and Glenoids.

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SPECIFIC DIAGNOSTIC INDICATIONS

The Anatomical Shoulder Cemented Humeral Stem is intended for cemented use in treatment of the following:

1. Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
2. Fractures or avascular necrosis.
3. Conditions consequent to earlier operations.

SUBSTANTIAL EQUIVALENCE

The Anatomica Shoulder Cemented Humeral Stem is similar to the Sulzer Orthopedics Select Shoulder CoCr Humeral Stem Prosthesis, the Orthomet/3M Modular Neer II Shoulder System, the Zimmer Fenlin Total Shoulder, the Smith & Nephew Richards Cofield Shoulder, the Kirschner/Biomet Atlas Shoulder, the Kirschner/Biomet Mod II-C Shoulder, the Biomet Bio-Modular Total Shoulder, and the Depuy Global Total Shoulder System.

Static and Dynamic Testing indicated that the device would survive physiologic loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Mr. Mitchell A. Dhority
Manager, Regulatory & Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K003832
Trade Name: Sulzer Orthopedics Anatomical Shoulder Cemented Humeral Stem
Regulatory Class: II
Product Code: KWS, HSD
Dated: December 8, 2000
Received: December 11, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003832

Device Name: Anatomical Shoulder Cemented Humeral Stem

Indications for Use:

The Anatomical Shoulder Cemented Humeral Stem is intended for cemented use in treatment of the following:

1. Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
2. Fractures or avascular necrosis.
3. Conditions consequent to earlier operations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003832

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)